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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Agus et al. Attorney Docket #: 39740-0008A
Serial No. 10/758,307 Group Art Unit 1632
Filing Date January 14, 2004 Examiner: Unassigned
Title: **GENE EXPRESSION MARKERS FOR BREAST CANCER PROGNOSIS**
Express Mail Label No.: **EV 582 629 346 US**
Mailing Date: **March 2, 2005**

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97

MAIL STOP: AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication except U.S. patents and patent application publications (1276 OG 55), is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98. In addition, enclosed is a copy of the International Search Report received in a related matter for the above-identified application which discloses the reference submitted herewith.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☒ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

☒ a certification as specified in §1.97(e) is provided below; **or**

☐ a fee of **\$180.00** as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

A. a certification as specified in §1.97(e) is completed below; and

B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**

C. a fee of \$180.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of **\$0.00** and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. **08-1641 (Attorney's Docket No. 39740-0008A)**.

Respectfully submitted,

Dated: March 2, 2005

By: 

David C. Foster (Reg. No. 44,685)

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INFORMATION DISCLOSURE
STATEMENT

PTO-1449

ATTY. DOCKET NO.:

39740-0008A

SERIAL NO.:

10/758,307

APPLICANT : David Agus, et al.

FILING DATE: January 14, 2005

GROUP: 1632

FOREIGN PATENT DOCUMENTS

| EXAMINER'S INITIALS | PATENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|------------------------|-----------------|------------|---------|-------|----------|--------------------------|-------------------------------------|
| | | | | | | YES | NO |
| | WO 02/10436 | 2-07-2002 | PCT | C12Q | 1/00 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | WO 03/078662 A1 | 9-25-2003 | PCT | C12Q | 1/68 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | WO 02/46467 A2 | 6-13-2002 | PCT | C12Q | 1/68 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | WO 00/55180 | 9-21-2000 | PCT | C07K | | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | WO 01/75160 A1 | 10-11-2001 | PCT | C12Q | 1/68 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | WO 00/55173 | 9-21-2000 | PCT | C07H | 21/04 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | WO 02/059271 A2 | 8-01-2002 | PCT | C12N | | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|--|---|
| | Ahmad, Athar, et al., "Stromelysin 3: An Independent Prognostic Factor for Relapse: Free Survival in Node-Positive Breast Cancer and Demonstration of Novel Breast Carcinoma Cell Expression", American Journal of Clinical Pathology, Vol. 152, No. 3, pp 721-728, March 3, 1998 |
| | Borresen-Dale, A. L. et al, "Genetic Profiling of Breast Cancer: From Molecular Portraits to Clinical Utility", The International Journal of Biological Markers, Vol. 18, No. 1, pp 54-56, September 20, 2002 |
| | Chenard, Marie-Pierre, et al., "High Levels of Stromelysin-3 Correlate with Poor Prognosis in Patients with Breast Carcinoma", The Journal of Molecular Diagnostics, Vol. 69, No. 6, pp 448-451, 1996 |
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| | Forozan, Farahnaz, et al., "Comparative Genomic Hybridization Analysis of 38 Breast Cancer Cell Lines: A Basis for Interpreting Complementary DNA Microarray Data", Cancer Research, Vol. 60, No. 16, pp 4519-4525, August 15, 2000 |
| | Guérin, Martine, et al. "Structure and Expression of <i>cerbB2</i> and EGF Receptor Genes in Inflammatory and Non-Inflammatory Breast Cancer", International Journal of Cancer, Vol. 43, pp 201-208, 1989 |
| | Leek, Russell, et al., "Association of Macrophage Infiltration with Angiogenesis and Prognosis in Invasive Breast Carcinoma", Cancer Research, Vol. 56, pp 4625-4629, October 15, 1996 |
| | Murray, P. A., et al., "The Prognostic Significance of Transforming Growth Factors in Human Breast Cancer", British Journal of Cancer, Vol. 67, No. 6, pp 1408-1412, 1993 |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | |
|---|---|---|
| INFORMATION DISCLOSURE STATEMENT PTO-1449 | ATTY. DOCKET NO.: 39740-0008A | SERIAL NO.: 10/758,307 |
| | APPLICANT : David Agus, et al. | |
| | FILING DATE: January 14, 2005 | GROUP: 1632 |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
| | Raschellá, Giuseppe, et al., "Expression of <i>B-myl</i> in Neuroblastoma Tumors is a Poor Prognostic Factor Independent from MYCN Amplification", Cancer Research, Vol. 59, pp 3365-3368, July 15, 1999 | |
| | Samuels-Lev, Yardena, et al., "ASPP Proteins Specifically Stimulate the Apoptotic Function of p53", Molecular Cell, Vol. 8, pp 781-794, October 2001 | |
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| | Sens, Mary Ann et al., "Metallothionein Isoform 3 Overexpression is Associated with Breast Cancers having a Poor Prognosis", American Journal of Pathology, Vol. 159, No. 1, July 2001 | |
| | Sgroi, Dennis C., et al., "In Vivo Gene Expression Profile Analysis of Human Breast Cancer Progression", Cancer Research, Vol. 59, No. 22, pp 5656-5661, November 15, 1999 | |
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| | van't Veer, Laura, et al. "Gene Expression Profiling Predicts Clinical Outcome of Breast Cancer", Nature, Vol. 415, No. 6871, January 31, 2002 | |
| EXAMINER | | DATE CONSIDERED |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



CERTIFICATION

(Attachment to Information Disclosure Statement)

- ☒ 37 C.F.R. §1.97(e)(1). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement; or
- ☐ 37 C.F.R. §1.97(e)(2). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing this certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement.

Respectfully submitted,

Dated: _____

March 2, 2005

By: _____

David C. Foster
David C. Foster (Reg. No. 44,685)



Please type and sign (+) inside this box []



PTO/SB/21 (6-99)

Approved for use through 09/30/2000. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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|--|-----------------------------|-------------------------------|-------------|
| TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i> | Application Number | 10/758,307 | |
| | Filing Date | January 14, 2004 | |
| | First Named Inventor | David AGUS et al. | |
| | Group/Art Unit | 1632 | |
| | Examiner Name | Unassigned | |
| Total Number of Pages in This Submission | | Attorney Docket Number | 39740-0008A |

| ENCLOSURES (check all that apply) | | |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Version with Markings Showing Changes <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input checked="" type="checkbox"/> Information Disclosure Statement and PTO-1449 <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> Request for Refund | <input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below): 22 references submitted, copy of International Search Report and a stamped return postcard. |
| Remarks | | |
| AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT 08-1641 FOR ANY FEES DUE IN CONNECTION WITH THIS PAPER. | | |

| SIGNATURE OF APPLICANT, ATTORNEY OR AGENT | | | |
|---|---|------------------|-------|
| Firm or Individual name | David C. Foster, Reg. No. 44,685 HELLER EHRMAN WHITE & McAULIFFE LLP | | |
| Signature | | | |
| Date | March 2, 2005 | Customer Number: | 25213 |

| CERTIFICATE OF MAILING | | | |
|--|---------------|------|---------------|
| I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail" (EV 582 629 346 US) on the date indicated below and addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 | | | |
| Typed or printed name | Sandra Puljic | | |
| Signature | | Date | March 2, 2005 |